IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

W.L. GORE & ASSOCIATES, INC., and GORE ENTERPRISE HOLDINGS, INC., Plaintiffs, v. MEDTRONIC, INC., MEDTRONIC USA, INC., and MEDTRONIC VASCULAR INC., Defendants	C.A. No. 10-cv-00441-MSD-DEM

W.L. GORE & ASSSOCIATES, INC. AND GORE ENTERPRISE HOLDINGS, INC.'S BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANTS' INEQUITABLE CONDUCT COUNTERCLAIM UNDER FED. R. CIV. P. 12(b)(6)

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

PAGE

CASES

STATUTES

OTHER AUTHORITIES

I. INTRODUCTION

Gore submits this brief in support of its motion to dismiss Medtronic's inequitable conduct allegations. In the seminal case of *Therasense, Inc. v. Becton Dickinson & Co.*, the Federal Circuit recently described inequitable conduct as a "plague" on both the courts and the patent system. *See* 2011 U.S. App. LEXIS 10590, at *29-30 (Fed. Cir. May 25, 2011). It is an apt description for Medtronic's allegations in this case.

Medtronic accuses two of the inventors of U.S. Patent No. 5,810,870 (the "'870 patent"), Wayne House and David Myers, of perpetrating a fraud on the Patent Office. In support of its claims attacking the integrity of these two scientists, Medtronic has made conclusory, unsupported allegations that:

1) Mr. House and Mr. Myers intentionally withheld "material" prior art, despite the fact that the references Medtronic cites describe the use of ePTFE ***in an orthopedic brace or a wet suit*** or to ***coat a wire***, whereas the '870 patent relates to stent grafts to repair aortic aneurisms;

2) Mr. House and Mr. Myers "mischaracterized" references that they themselves disclosed to the Patent Office; and

3) Mr. House's and Mr. Myers's submission of a standard inventor oath on a Patent Office form document – something required of every patent applicant – constitutes a "false affidavit" that brings this case outside the core holding of *Therasense.*

As explained in detail below, none of Medtronic's allegations have merit and none satisfy the requirements for pleading inequitable conduct. Gore respectfully requests that the Court dismiss Medtronic's inequitable conduct counterclaim under Federal Rule of Civil Procedure 12(b)(6).

II. STATEMENT OF FACTS

The '870 patent issued on September 22, 1998 to inventors David Myers, James Lewis, Wayne House, and Karl Schwarz. (D.I. 69, Ex. A at 1.) The '870 patent issued from U.S. App.

No. 08/479,931 ("the '931 application"), a "divisional" application stemming from an earlier patent application, U.S. App. No. 08/109,214 ("the '214 application"). (*Id*. at 1.) The parent '214 application issued as U.S. Patent No. 5,735,892. (*Id*. at 1.) Later, the '931 application issued as the '870 patent. Inventor Wayne House, a registered patent agent, prosecuted both applications. (*Id*. at 1.)

The '870 patent claims intraluminal stent grafts. One use of stent grafts is to treat aortic aneurisms by substituting the stent graft for a portion of a blood vessel that has weakened and is subject to rupture. (*Id*. at 1:37-43.) The stents grafts of the '870 patent comprise a diametrically adjustable stent, a covering less than 0.1 mm thick, and a seam extending through the covering; the patent also claims methods of making stent grafts. (*Id*. at 9:31-43, 10:5-24, 10:31-34.) The patent describes expanded polytetrafluoroethylene ("ePTFE") as one material that can be used for the covering. (*Id*. at 1:15-20.) ePTFE has many known applications, including in various medical implants, fabrics, fibers, wires, cables, gaskets and sealants, vents, cartridges, and filtration bags and membranes. Naturally, these widely varied uses of ePTFE have widely varying requirements for uniformity, strength, flexibility, and other properties of the material.

Medtronic's counterclaim alleges three bases for inequitable conduct. ***First***, Medtronic alleges that Mr. House committed inequitable conduct when he failed to disclose U.S. Patent Nos. 5,358,516 ("the '516 patent") and 5,397,628 ("the '628 patent"), and that Mr. Myers likewise committed inequitable conduct when he failed to disclose the '516 patent. (D.I. 69 at ¶¶ 45, 48.) ***Second***, Medtronic alleges that Mr. House and Mr. Myers "mischaracterized and misrepresented" several additional references to the Patent Office, specifically United States Patent Nos. 5,123,917 ("the '917 patent"), 5,107,852 ("the '852 patent"), and 4,768,507 ("the '507 patent"), and DE 3,918,736 ("the '736 patent"). (*Id*. at ¶¶ 46, 49.) ***Third***, Medtronic

alleges that Mr. House and Mr. Myers "filed a false affidavit by signing a declaration as an alleged inventor" when they knew of the '516 patent, the '628 patent, the '917 patent, the '852 patent, the '507 patent, and/or the '736 patent. (*Id*. at ¶¶ 47, 50.) Facts related to each of these allegations are addressed below.

A. Medtronic's Allegations that Mr. House and Mr. Myers Withheld the '516 and '628 Patents with the Intent to Deceive the Patent Office

Medtronic's allegations concerning the '516 and '628 patents are pled on information and belief and contain no more than conclusory allegations that these references were "but-for" material to the patentability of the '870 patent (*i.e.,* the Patent Office allegedly would not have granted the '870 patent if it were aware of either reference) and that Mr. House and Mr. Myers withheld them "with the specific intent to deceive the PTO." (*Id*. at ¶¶ 45, 48.) These types of conclusory allegations alone are sufficient to grant Gore's motion to dismiss, but additional facts further support dismissal.

Both the '516 and the '628 patents describe technology vastly different than the technology in the '870 patent. The '516 patent describes an electrophysiology lead (a wire carrying an electrical current) in which the wire is coated with porous PTFE tubing. (D.I. 69, Ex. B at 2:5-11.) Despite the obvious physical and functional differences between an electrical lead and a stent graft, Medtronic alleges without support that the '516 patent "solves the prior art problem" allegedly solved by the '870 patent. (D.I. 69 at ¶ 59.) Medtronic also alleges that both the '516 and '870 patents use "a covering of porous PTFE coated with FEP" (*id*. at ¶ 59), while ignoring the fact that FEP is used for entirely different purposes in the two patents – the '870 patent describes using FEP as an adhesive to attach a covering to a stent (D.I. 69, Ex. A at 7:59-63), while the '516 patent discloses applying an FEP coating to a wire for insulation (D.I. 69, Ex. B at 2:26-32). Medtronic also alleges that the '516 patent discloses a covering of ePTFE less

than 0.1 mm thick (D.I. 69 at ¶ 59), but again ignores the application, a coating of a wire, compared to a tube of material that acts as a "replacement" blood vessel. (*Id*. at 1:37-43.)

The '628 patent describes a "body protection material" comprising an outer layer of cellular rubber and an inner layer of ePTFE. (D.I. 69, Ex. C at 1:51-54.) The stated purpose of the inner layer of ePTFE is to "increase [the] wearing comfort of cellular rubber wet suits and orthopedic braces." (*Id*. at 1:54-57.) Again, Medtronic ignores the obvious physical and functional differences between those types of applications and the stent grafts of the '870 patent. Instead Medtronic categorizes an orthopedic brace as a "medical device" somehow akin to a stent graft, and claims that the '628 patent thus discloses using ePTFE less than 0.1 mm thick as a "covering for medical devices." (D.I. 69 at ¶ 62.)

Medtronic's allegations that Mr. House and Mr. Myers intended to deceive the Patent Office are further contradicted by the '870 patent's prosecution history. During the prosecution of the original '214 application, the applicants disclosed over sixty prior art references. (Ex. 1 at GOR_VA0023680-88, GOR_VA0023693-94, GOR_VA0023702-03.)[1] The Examiner acknowledged the receipt of these references, and expressly instructed the applicants to "eliminate irrelevant and marginally pertinent cumulative references as the citation of such volumes of marginal references only distracts [from] the patentability determination." (*Id*. at GOR_VA0023706.)

Other information in the '870 patent confirms that the two references on which Medtronic seeks to rely are exactly the type of "marginally pertinent cumulative references" to

[1] Ex. 1 is the prosecution history of the '214 application, the parent application of the '870 patent. Although this part of the '870 patent's intrinsic record was not attached as an exhibit to Medtronic's counterclaim, the Court may consider matters of public record, such as this publicly available document, when reviewing a motion to dismiss under Rule 12(b)(6). *See Secretary of State for Defence v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007).

which the Examiner referred. In particular, another reference cited in the specification, U.S. Patent No. 3,953,566 ("the '566 patent") (D.I. 69, Ex. A at 4:23-24), discloses ePTFE films less than 0.1 mm thick. (*See* Ex. 2 at Table 6 (describing ePTFE film with thickness of 3.7 mils (0.09 mm).) Thus, Medtronic's basis for alleging that the '516 and '628 patents are material – that they disclose ePTFE films less than 0.1 mm thick, albeit in two very different applications than stent grafts – is contradicted by the '870 patent itself, which discloses a reference describing ePTFE films less than 0.1 mm thick.

B. Medtronic's Allegations that Mr. House and Mr. Myers Mischaracterized the '917, '852, '507, and '736 Patents with the Intent to Deceive the Patent Office

Medtronic's allegations that Mr. House and Mr. Myers "mischaracterized" the '917 patent, the '852 patent, the '507 patent, and the '736 patent are again limited to conclusory statements, made on information and belief, that these inventors "mischaracterized material information with the specific intent to deceive the PTO." (D.I. 69 at ¶¶ 46, 49.) Again, these types of conclusory allegations are insufficient to support a claim of inequitable conduct, but additional facts further support Gore's motion to dismiss.

The '917 patent, '852 patent, and '736 patent were each cited on an Information Disclosure Statement submitted by the applicants to the Patent Office during the prosecution of the '214 application. (Ex. 1 at GOR_VA0023680-88.) The European counterpart of the '507 patent, WO 87/04935, was submitted by the applicants in a Supplemental Information Disclosure Statement during the prosecution of the '214 application. (*Id*. at GOR_VA0023702-03.)

The Examiner considered each of these references, as demonstrated by her initials beside each of them on the Information Disclosure Statements, and allowed the '870 patent to issue over each of these references. (*Id*. at GOR_VA0023684-86, GOR_VA0023703.) Medtronic's inequitable conduct counterclaim does not explain how Mr. House or Mr. Myers could have

"misrepresented" references that they provided to the Examiner and that the Examiner considered.

C. Medtronic's Allegations that Mr. House and Mr. Myers Filed False Affidavits with the Patent Office

Medtronic's allegations that Mr. House and Mr. Myers "filed a false affidavit by signing a declaration as an alleged inventor" are also conclusory and pled on information and belief. (D.I. 69 at ¶¶ 47, 50.) The "false affidavit" Medtronic refers to is a Patent Office form, Form PTO-SB-110, in which each inventor declares a belief that he or she is the first inventor of the subject matter claimed in the application. (D.I. 69, Ex. H at MED0002791-94.)

Medtronic alleges that the Patent Office form that Mr. House and Mr. Myers submitted was "false" because Mr. House allegedly knew that the '516 patent, '628 patent, '917 patent, '852 patent, '507 patent, and '736 patent "disclosed the use of thinner (less than 0.10 mm) ePTFE coverings with medical devices, including stents," and that Mr. Myers allegedly knew that the '516 patent and '852 patent contained this information. (D.I. 69 at ¶¶ 47, 50.) As explained above, Medtronic's allegations that the '516 and '628 patents were material are not supported by the disclosures in those references, and the '917, '852, '507, and '736 patents were disclosed to the Examiner during prosecution.

Further, every patent applicant is ***required*** to submit Form PTO-SB-110 as part of every utility patent application. 35 U.S.C. § 115; 37 CFR 1.63. As a result, this allegation of "false affidavit" is nothing more than a common "failure to disclose" allegation dressed up as something more.

D. Other Incorrect Allegations Contained in Medtronic's Inequitable Conduct Counterclaim

Medtronic's inequitable conduct allegations share another common thread, namely, that the inventors represented to the Patent Office that a covering of ePTFE less than 0.1 mm thick

was the sole "improvement over the prior art" described in the '870 patent. (D.I. 69 at ¶¶ 52-54.) Although Medtronic cites sections of the specification as purportedly supporting this allegation, these sections relate to two specific prior art references, not to what the applicants regarded as their inventions. (D.I. 69, Ex. A at 1:58-2:25.)

Medtronic alleges that "[t]he '870 patent asserts that the problem with the tubular, diametrically adjustable stents with a tubular covering of expanded polytetrafluoroethylene ***in the prior art*** are the 'relatively thick, bulky wall' of the expanded polytetrafluoroethylene covering." (D.I. 69 at ¶ 53 (emphasis added).) Medtronic also alleges that "[t]he '870 patent claims the thinness ***of the prior art*** was limited by the difficulty of manufacturing an extruded, longitudinally expanded tube having a thin wall of uniform thickness." (*Id*. at ¶ 53 (emphasis added).) Medtronic concludes by alleging that "[t]he '870 patent alleges the improvement ***over the prior art*** is a tubular covering of porous expanded polytetrafluoroethylene attached to a tubular, diametrically adjustable stent, said tubular covering being less than about 0.10 mm thick." (*Id*. at ¶ 54 (emphasis added).)

The sections of the specification that Medtronic cites in support of these allegations, however, refer not to the "prior art" in general, but to two specific patents—the '917 patent discussed above, and U.S. Patent No. 5,122,154 ("the '154 patent"). (D.I. 69, Ex. A at 1:58-2:25.) The specification notes that these two references describe "endovascular bypass grafts for intraluminal use," each of which include a "sleeve" made of ePTFE. (*Id*. at 2:4-15.) The specification then describes that using ***these particular grafts*** as sleeves over a stent is difficult because "the relatively thick, bulky wall of the extruded, longitudinally expanded PTFE tubes limits the ability of the tube to be contracted into a small cross-sectional area for insertion into a blood vessel." (*Id*. at 2:15-20.)

Likewise, Medtronic makes a related allegation that Mr. House committed inequitable conduct when he allegedly failed to disclose Gore's capability to manufacture ePTFE film less than 0.1 mm thick. (*Id*. at ¶¶ 57, 64.) However, as explained above the '870 specification discloses the '566 patent (D.I. 69, Ex. A at 4:23-24), which is assigned to Gore, and describes ePTFE films less than 0.1 mm thick. (*See* Ex. 2 at Table 6 (describing ePTFE film with thickness of 3.7 mils (0.09 mm).) Notably, the '566 patent does not describe using these thin ePTFE films with vascular grafts or stent grafts, and Medtronic's pleading does not allege that Gore was capable of manufacturing ePTFE films less than 0.1 mm thick that were suitable for use with stent grafts before the inventions claimed in the '870 patent. Instead, Medtronic makes only a generic allegation that Gore "had been using or considering using the film of this thickness with ***medical devices***." (D.I. 69 at ¶ 57 (emphasis added).) As explained above, the "medical devices" Medtronic refers to in its pleading are an electrical lead wire, an orthopedic brace, and a wet suit.

III. LEGAL STANDARDS

In deciding a motion to dismiss, a court should "begin by taking note of the elements a plaintiff must plead to state a claim." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1946 (2009). Medtronic's answer makes a counterclaim for inequitable conduct, which contains two distinct elements: (1) "that the applicant misrepresented or omitted material information" (the "materiality" element) and (2) that the applicant did so "with the specific intent to deceive the PTO" (the "intent" element). *Therasense*, 2011 U.S. App. LEXIS 10590 at *24.

With respect to the materiality element, "the materiality required to establish inequitable conduct is 'but-for' materiality," meaning that "the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at *37. A limited exception to the "but-for materiality" requirement exists that permits misconduct to be deemed material without "but-for"

proof in "cases of affirmative egregious misconduct," including, for example, cases of "bribery and suppression of evidence" or the submission of an "unmistakably false affidavit." *Id.* at *39-42.

With respect to the intent element, the requisite intent is "a specific intent to deceive the PTO," which requires that "the applicant ***made a deliberate decision*** to withhold a ***known*** material reference." *Id.* at *32 (internal quotation marks omitted) (emphasis in original). "[G]ross negligence" is not enough, nor is it enough that that "the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO." *Id.* at *32-33.

The intent to deceive must be "the single most reasonable inference able to be drawn." *Id.* at *34 (internal quotation marks omitted).

The next step in deciding a motion to dismiss is to assess the sufficiency of the allegations actually pled. *Iqbal*, 129 S.Ct. at 1949-50. In assessing whether a claim of inequitable conduct has been sufficiently pled, the general pleading requirements of Rule 8(a) apply to the intent element, and the particularity requirements of Rule 9(b) apply to the materiality element. *See Pfizer Inc. v. Teva Pharms. USA, Inc.*, --- F. Supp. 2d. ----, 2011 WL 3563112, at *16 (E.D. Va. Aug. 12, 2011) (explaining that "[i]n pleading the intent prong, the court evaluates whether a sufficient showing has been made under the standards of Federal Rule of Civil Procedure 8(a)" but that "a party must still identify the specific who, what, when, where, and how of the material misrepresentation or omission committed" (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009)).

To satisfy the particularity requirements of Rule 9(b), the factual allegations supporting an inequitable conduct allegation must "identify the specific who, what, when, where, and how of the material misrepresentation or omission." *Pfizer*, 2011 WL 3563112 at *16 (quoting

Exergen, 575 F.3d at 1328). The particularity requirement is not satisfied by "[a] mere recitation that 'X' individual, at 'X' time, failed to turn over 'X' information to the PTO that would have been material to the prosecution, with specific intent to deceive the PTO." *Pfizer*, 2011 WL 3563112 at *16.

To identify the sufficiency of the allegations pled, the court first identifies "the allegations in the complaint that are not entitled to the assumption of truth." *Iqbal*, 129 S.Ct. at 1951. That process primarily involves "separating the legal conclusions from the factual allegations" in the complaint. *A Society Without a Name v. Virginia*, --- F.3d ----, 2011 WL 3690000, *2 (4th Cir. Aug. 24, 2011).

When there are exhibits and matters of public record that are properly considered, the court need not "accept as true allegations [from the complaint] that contradict matters properly subject to judicial notice or by exhibit." *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002) (internal quotation marks omitted). Likewise, the court need not "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice," and the court need not accept "legal conclusion couched as factual allegation." *Iqbal*, 129 S.Ct. at 1949-50.

The court then determines whether, after identifying those allegations that are not entitled to the assumption of truth, there are any "well-pleaded factual allegations." *Iqbal*, 129 S. Ct. at 1950. If there are, "a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Id.* at 1950-51. A complaint plausibly gives rise to an entitlement to relief only if "the factual content of the complaint 'allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Nemet*

Chevrolet, Ltd. v. Consumeraffairs.com, Inc., 591 F.3d 250, 255 (4th Cir. 2009) (quoting *Iqbal*, 129 S.Ct. at 1949).

IV. DISCUSSION

A. Medtronic's Allegations that Mr. House and Mr. Myers Withheld the '516 and '628 Patents with the Intent to Deceive the Patent Office Do Not Satisfy the Requirements for Pleading Inequitable Conduct

To satisfy the pleading requirements for inequitable conduct, Medtronic's allegations concerning the '516 and '628 patents must allow the Court to draw the reasonable inference that these references were "but-for" material to the patentability of the '870 patent and that Mr. House and Mr. Myers withheld them with the specific intent to deceive the Patent Office. Because Medtronic's allegations do not satisfy either inquiry, they should be dismissed.

With respect to materiality, as explained above, the '516 patent describes an ePTFE coating on an electrical lead wire, and the '628 patent describes a layer of ePTFE used to increase the comfort of an orthopedic brace or a wet suit. (D.I. 69, Ex. B at 2:5-11; *Id*., Ex. C at 1:51-57.) On their face, these references are far afield from the stent grafts and methods of making stent grafts described and claimed in the '870 patent, including the application of ePTFE as a covering for stent grafts. Indeed, there are hundreds, if not thousands, of U.S. patents that describe various types of ePTFE and various uses for ePTFE, many of which have different requirements for uniformity, strength, flexibility, and other properties. The use of ePTFE as a wire coating, or as a layer of an orthopedic brace or wet suit, provides little or no information about the use of ePTFE as a type of covering on a stent graft.

Medtronic's only apparent argument for why the '516 and '628 patents are allegedly material is that they describe (in two very different applications than stent grafts) a layer of ePTFE film less than 0.1 mm thick. (D.I. 69 at ¶¶ 59, 61-62.) However, the applicants disclosed a reference that describes ePTFE films less than 0.1 mm thick – the '566 patent – in the '870

patent specification. (D.I. 69, Ex. A at 4:23-24; Ex. 2 at Table 6.) To the extent that the general ability to make ePTFE films less than 0.1 mm thick (as opposed to ePTFE films with the specific properties necessary for use in stent grafts) was material to the '870 patent, that information ***was already disclosed*** to the Patent Office during prosecution. (*Id*.) Thus, the '516 and '628 patents, even if considered material, are at best cumulative of references disclosed to the Patent Office, and thus cannot be "but-for" material. *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009) ("[A] withheld otherwise material reference is not material if it is merely cumulative to, or less relevant than, information already considered by the examiner.").

Medtronic's conclusory allegations concerning the disclosures in the '516 and '628 patents are contradicted by the exhibits attached to Medtronic's pleading, namely the '870 patent specification and the references themselves. They should not be accepted as true by the Court. *Veney*, 293 F.3d at 730. Further, Medtronic's only allegations that these references were "but-for" material to the patentability of the '870 patent (D.I. 69 at ¶¶ 45, 48, 62) are "mere conclusory statements" pled on information and belief that are not sufficient to satisfy the requirements for pleading inequitable conduct. *Iqbal*, 129 S. Ct. at 1949-50; *Pfizer*, 2011 WL 3563112 at *16; *see also Veney*, 293 F.3d at 730.

With respect to intent, Medtronic similarly pleads only a conclusory allegation, on information and belief, that Mr. House and Mr. Myers withheld these allegedly material references "with the specific intent to deceive the PTO." (D.I. 69 at ¶¶ 45, 48.) Although intent may be averred generally, "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 129 S. Ct. at 1949-50, 1954. Medtronic's allegations concerning Mr. House's and Mr. Myers's purported intent are conclusory,

unsupported recitations of the intent prong of the inequitable conduct standard, and are insufficient under *Iqbal*. *Id*. at 1954.

Medtronic's only other allegation resembling an allegation of intent is an attempted nod to *Therasense.* Specifically, Medtronic alleges that there "is no credible explanation for the failure of House to disclose the '516 and '628 prior art to the PTO." (D.I. 69 at ¶ 63.) Under *Therasense*, however, the intent to deceive must be "the single most reasonable inference able to be drawn." 2011 U.S. App. LEXIS 10590 at *34. In this case, the Examiner had expressly instructed Mr. House during prosecution to "eliminate irrelevant and marginally pertinent cumulative references as the citation of such volumes of marginal references only distracts [from] the patentability determination." (Ex. 1 at GOR_VA0023706.)

As explained above, the '516 and '628 patents are precisely the types of "irrelevant and marginally pertinent cumulative references" that the Examiner instructed Mr. House not to submit. Contrary to Medtronic's allegation that there is no other explanation for Mr. House's conduct, it is equally reasonable, if not more reasonable, to infer that Mr. House was simply following the Examiner's instruction. *See Therasense*, 2011 U.S. App. LEXIS 10590 at *33 ("Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.").

In sum, Medtronic's allegations concerning the '516 and '628 patents do not allow "the Court to draw the reasonable inference" that these references are "but-for" material and that Mr. House and Mr. Myers withheld them with the specific intent to deceive the Patent Office, as required by Rule 8(b). *Nemet*, 591 F.3d at 255. Further, Medtronic's allegations concerning the purported materiality of these references are contradicted by the references themselves, and do not meet the pleading requirements of Rule 9(b). *Pfizer*, 2011 WL 3563112 at *16.

B. Medtronic's Allegations that Mr. House and Mr. Myers Mischaracterized References to the Patent Office Do Not Satisfy the Requirements for Pleading Inequitable Conduct

Medtronic's allegations that Mr. House and Mr. Myers "mischaracterized and misrepresented" several references disclosed to the Examiner, the '917 patent, the '852 patent, the '507 patent, and the '736 patent (D.I. 69 at ¶¶ 46, 49), are also meritless.

First, Medtronic's allegations are premised upon its incorrect claim that the '870 patent specification states that an ePTFE covering less than 0.1 mm thick is the sole "improvement in the prior art." (*Id*. at ¶¶ 52-54.) As explained above, the statements cited by Medtronic do not support that claim, but instead establish that the applicants were describing problems with two specific prior art references. (D.I. 69, Ex. A at 1:58-2:25.)

Second, Medtronic's allegations regarding Mr. House's and Mr. Myers's specific intent to "mischaracterize" these references to the Patent Office are again limited to conclusory statements, made on information and belief. (*Id*. at ¶¶ 46, 49.) The Court need not, and should not, "accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Veney*, 293 F.3d at 730.

Indeed, it is unreasonable to infer that Mr. House or Mr. Myers mischaracterized, or had the intent to mischaracterize, any of the references identified by Medtronic. The record shows that the applicants (through Mr. House who was acting as the patent agent) submitted each of the '917 patent, the '852 patent, the '736 patent, and the European counterpart of the '507 patent (WO 87/04935) to the Patent Office during the prosecution of the '214 application, the parent application of the '870 patent. (Ex. 1 at GOR_VA0023680-88, GOR_VA0023702-03.) The Examiner considered each of these references (as demonstrated by her initials beside each reference), and issued the '870 patent. (*Id*. at GOR_VA0023684-86, GOR_VA0023703.)

In light of these facts, Medtronic's allegations that Mr. House and Mr. Myers deliberately mischaracterized the references do not make sense. They submitted the very references to the Examiner. Accepting Medtronic's allegations also requires finding that the Examiner relied on these alleged "mischaracterizations" despite the fact that she considered each of the references before issuing the '870 patent. Medtronic's allegations regarding the '917 patent further rest on a false premise that the applicants were required to summarize the entire disclosure of the '917 patent within the '870 patent specification (D.I. 69 at ¶¶ 66-69), despite the fact that they disclosed the '917 patent to the Examiner. There is no such requirement in the law.

Medtronic's conclusory allegations, made on information and belief, are contradicted by the facts in the record and do not permit a reasonable inference that Mr. House or Mr. Myers mischaracterized the '917 patent, the '852 patent, the '507 patent, and/or the '736 patent with the specific intent to deceive the Patent Office. *Veney*, 293 F.3d at 730; *Nemet*, 591 F.3d at 255.

C. Medtronic's Allegations that Mr. House and Mr. Myers Submitted False Affidavits Do Not Satisfy the Requirements for Pleading Inequitable Conduct

Medtronic's final purported basis for alleging inequitable conduct is that Mr. House and Mr. Myers "filed a false affidavit by signing a declaration as an alleged inventor" when they knew of the '516 patent, the '628 patent, the '917 patent, the '852 patent, the '507 patent, and/or the '736 patent. (D.I. 69 at ¶¶ 47, 50.) These allegations are again conclusory statements, made on information and belief (*id*. at ¶¶ 47, 50), that the Court need not and should not accept. *Veney*, 293 F.3d at 730. Further, these allegations are premised upon Medtronic's claim that the '870 patent specification states that an ePTFE covering less than 0.1 mm thick is the sole "improvement in the prior art," which as explained above, is incorrect. (*Id*. at ¶¶ 47, 50; *see also Id*. at ¶¶ 52-54.)

Medtronic's "false affidavit" allegation is really an attempt to disguise a standard "failure to disclose" allegation – the type that *Therasense* abhors – as something more. Specifically, by alleging a "false affidavit," Medtronic is attempting to trigger the limited exception to "but-for" materiality set forth in *Therasense*. The exception permits conduct to be deemed material without "but-for" proof in egregious cases, including, for example, cases of "bribery and suppression of evidence" or the submission of an "unmistakably false declaration." *Therasense,* 2011 U.S. App. LEXIS 10590 at *38, 42.

The problem with Medtronic's tactic is that the "declaration" it refers to in its pleading is a Patent Office form that is required of ***every*** applicant that submits a utility patent application (Form PTO SB 110). 35 U.S.C. § 115; 37 CFR 1.63. As a result, ***every*** alleged failure to submit material prior art involves the same "affidavit" that Medtronic now cites as part of its allegations. Medtronic's argument is simply an end-run around the high standard the Federal Circuit rightfully applied to cases just like this one. Indeed, contrary to Medtronic's argument, *Therasense* makes clear that "neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct." *Therasense*, 2011 U.S. App. LEXIS 10590 at *40. Thus, Medtronic's allegations based on the required submission of Form PTO-SB-110 cannot stand as a matter of law.

Medtronic's conclusory allegations of intent, made on information and belief, are contradicted by the facts in the record. Mr. House and Mr. Myers submitted a form declaration required to be filed with every utility patent application, not the type of "unmistakably false affidavit" that can trigger the exception to "but-for" materiality under *Therasense. Id*. at *39. These allegations do not permit a reasonable inference that Mr. House or Mr. Myers is liable for the alleged misconduct, and should be dismissed along with the other allegations presented in

Medtronic's inequitable conduct counterclaim. *Nemet*, 591 F.3d at 255; *Pfizer*, 2011 WL 3563112 at *16.

V. CONCLUSION

For the reasons stated above, Gore respectfully requests that the Court dismiss Medtronic's inequitable conduct counterclaim under Federal Rule of Civil Procedure 12(b)(6).

Dated: October 11, 2011

Respectfully submitted,

FISH & RICHARDSON P.C.

By: */s/ Ahmed J. Davis*

Ahmed J. Davis (Va. Bar No. 43,972)
1425 K Street, NW, 11th Floor
Washington, DC 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331
Email: davis@fr.com

Timothy Devlin (admitted *pro hac vice*)
Susan M. Coletti (admitted *pro hac vice*)
Robert M. Oakes (admitted *pro hac vice*)
222 Delaware Avenue, 17th Floor
Wilmington, DE 19899-1114
Telephone: (302) 652-5070
Facsimile: (302) 652-0607
Email: tdevlin@fr.com; coletti@fr.com; oakes@fr.com

Juanita R. Brooks (admitted *pro hac vice*)
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099
Email: brooks@fr.com

Attorneys for Plaintiffs
W.L. GORE & ASSOCIATES, INC. and
GORE ENTERPRISE HOLDINGS, INC.

80114811.doc

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of W.L. GORE & ASSSOCIATES, INC. AND GORE ENTERPRISING HOLDINGS, INC.'S BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANTS' INEQUITABLE CONDUCT COUNTERCLAIM UNDER FED. R. CIV. P. 12(b)(6) has been served October 11, 2011, via the Court's ECF system upon all counsel designated to receive such notices, as identified below:

Dabney J. Carr, IV
Robert A. Angle
TROUTMAN SANDERS LLP
1001 Haxall Point
Richmond, VA 23219
dabney.carr@troutmansanders.com
robert.angle@troutmansanders.com

Karen D. McDaniel
Thomas J. Leach
Rachel C. Hughey
MERCHANT & GOULD P.C.
3200 IDS Center, 80 South Eighth Street
Minneapolis, MN 55402
kmcdaniel@merchantgould.com
tleach@merchantgould.com
rhughey@merchantgould.com

Ryan J. Fletcher
MERCHANT & GOULD P.C.
1050 Seventeenth Street, Suite 1950
Denver, CO 80265
rfletcher@merchantgould.com
MGMedtronicServiceList@merchantgould.com

James J. Elacqua
SKADDEN ARPS
525 University Avenue, Suite 1100
Palo Alto, CA 94301
James.elacqua@skadden.com

/s/ Ahmed J. Davis
Ahmed J. Davis